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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,366	08/29/2006	Robert D. Black	9099.17	3158

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
NGUYEN, HIEN NGOC	

ART UNIT	PAPER NUMBER
3777	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,366	BLACK ET AL.	
	Examiner	Art Unit	
	HIEN NGUYEN	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-13,15-23,34 and 41-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-13,15-23,34 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/29/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/2010 has been entered.

Claim Objections

Claim 45 is objected to because of the following informalities: Claim 45 is depended on a cancel claim. Examiner suggests amend claim 45 to depend on claim 34. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 6, 10, 15-18, 34, 45, 48-49 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) and in view of Ritter et al. (US 2003/0153827).

3. Addressing claim 1, Mate discloses: a target locating and in vivo sensor system used with a therapy delivery and imaging source (see [0001] and [0009-0014]); an external solenoid member (see [0032-0039] and [0041-0048]); at least one implantable wireless unit comprising a solenoid, wherein, in operation, the unit solenoid is held internally in the patient and cooperates with the external solenoid to generate the coupling signal, wherein the coupling signal has a signal strength that varies based on the position of the external solenoid member relative to the at least one implantable unit (see [0041-0048] [0050], [0056-0061]); a computer module in communication with the controller configured to evaluated the coupling signal strength in relation to the position of the external solenoid/magnet and determine the position of at least one implantable wireless unit (see [0009-0014] and [0053]). However, Mate does not disclose a mechanism operably associated with the external solenoid member, wherein, in operation, the mechanism is configured to controllably move the solenoid external of a patient, wherein the mechanism comprises an articulating arm, and wherein the articulating arm is configured to move the external solenoid/magnet in a three-dimensional pattern in free space about a patient to generate a coupling signal. In the same field of endeavor, which is locating/tracking magnetic implant for therapy

procedure, Ritter discloses a mechanism operably associated with the external solenoid member, wherein, in operation, the mechanism is configured to controllably move the solenoid external of a patient, wherein the mechanism comprises an articulating arm, and wherein the articulating arm is configured to move the external solenoid/magnet in a three-dimensional pattern in free space about a patient to generate a coupling signal (see abstract, [0008-0011], [0022] and Fig. 2, element 206). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate to include a mechanism operably associated with the external solenoid member, wherein, in operation, the mechanism is configured to controllably move the solenoid external of a patient, wherein the mechanism comprises an articulating arm, and wherein the articulating arm is configured to move the external solenoid/magnet in a three-dimensional pattern in free space about a patient to generate a coupling signal as taught by Ritter because with the robot mechanical arm and magnet/solenoid at its tip surgeon can effectively keep track of the solenoid/sensor implant inside the body.

4. Addressing claims 6, 10, 17-18 and 49, Mate discloses a plurality of discrete sensor units (see [0036] and Fig. the system is capable of using the frequency of 500khz-1Mhz (this is just AC frequency supply to the external solenoid/magnet; the system can supply frequency in this range to the external solenoid). It would have been obvious design choice to one of ordinary skill in the art at the time of the invention to design the system to detect coupling signal at a depth of up to at least about 14 cm because this enable implant to be deeply implanted anywhere inside the patient body

and only require routine skill in the art. Mate use excitation markers and sensors to identify and track the position of the target and guide radiation beam. Internal excitation marker is located in or near the target. An external excitation source that is remotely excites the markers to produce an identifiable signal. Ritter discloses the mechanisms is an articulated arm and wherein the articulating arm is configured to move the magnet/solenoid in a three-dimensional pattern in free space to generate the coupling signal (see abstract, [0008-0011], [0021-0024] and Fig. 2, element 206; the magnet is the same as solenoid because they both generate magnetic field and coupling signal); and angular shift of the sensor unit is the same as changing orientation of the sensor (see abstract, [0008-0011], [0021-0024] and Fig. 2, element 206).

5. Addressing claims 15-16 and 48, it would have been obvious to one of ordinary skill in the art at the time of the invention that Mate's system in view of Ritter perform the functions in claims 15-16 and 48 because the system has to evaluate signal shape and strength coming from internal sensor in order to locate the internal sensor position. As disclose by Ritter above in abstract, [0008-0011], [0021-0024] and Fig. 2, element 206, the robot arm is moving through three dimensional spaces to determine the position of the sensor inside the patient body. The robot arm is moving to find the implant and come into contact with the implant. In order to detect and track the electromagnetic sensor inside the body the system/processor determine the signal strength/magnitude and orientation (see [0008-0011] and [0021-0024]).

6. Addressing claims 34, 45 and 55-57 and the computer program claim herein is substantially the same in scope as the system in claims 1 and 49 above. The system of claims 1 and 49 runs the computer program in claims 34, 45 and 55-57. Thus claims 34, 45 and 55-57 are rejected for at least the same reason as claims 1 and 49 above. Also see Mate [0009] and [0036], he discloses guiding radiation therapy, selectively transmit radiation dose. He has to have computer program in order for the system to perform this function.

7. Claims 2, 4-5, 7-9, 11-13, 19-23, 41-44, 46-47 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685), in view of Ritter et al. (US 2003/0153827) and further in view of Knapp et al. (WO 97/33513).

8. Addressing claims 23 and 41, the method claim herein is substantially the same in scope as the system in claims 1, 2 and 7 above. The system applied the method. Thus claim 23 and 41 are rejected for at least the same reason as claims 1, 2 and 7 above. Also see Mate [0009]. He tracks the position of the cancerous target and selectively applies radiation to the target. This is the same method as claim 41. Knapp discloses the missing limitation of claims 2 and 7 of sensing radiation and temperature using implanted sensors (see page 9, lines 30-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include sensors for sensing radiation and temperature as taught by Knapp because this would

enable the system to deliver radiation in the correct amount and to the correct location inside the body.

9. Addressing claim 42, Mate discloses positioning the patient in an imaging system in a registered position and obtaining an image of the target treatment site and at least one implanted sensor with the patient in the registered position in an imaging system (see [0060], the image show target site 12 and markers 30 therefore it is inherent the patient is in a registered position in order to have images of target site and markers). Ritter discloses aligning the coupling member to a fiducial marker/sensor associated with the imaging system relative to the registered position and obtaining an electrical measurement of signal strength of the coupling signal while the patient is in the registered position and the coupling member is aligned and held above the patient to define the initial spatial position correlated to signal strength of the at least sensor unit in three-dimensional space (see [0008-0011], [0021-0024] and Fig. 2).

10. Addressing claims 2, 4-5, 7-9, 11-13, 19-22, 43-44, 46-47 and 50-54, Mate further disclose sensor unit is a plurality of discrete sensor units (see [0036] and Figs. 4, 6); the coupling signal is a magnetic and wireless rf coupling signal (see [0036] and [0044]). However, Mate and Ritter do not explicitly disclose sensor configured to sense at least one predetermined parameter of interest in vivo; communicating with implanted sensor unit using a bit encoded RF signal; sensors with sensing parameter for temperature and radiation dose. Knapp discloses: sensor configured to sense at least

one predetermined parameter of interest in vivo (see page 9, lines 30-36); the external reader is configured to communicate with the implanted sensor unit using a bit encoded RF signal to communicate with many sensors, by using bit encoded Knapp can identify and separately communicate with each sensor (see abstract, page 3, lines 1-33, especially lines 4, 10 and 12, the hand held electromagnetic reader is the external reader; the transmitted encoded data is the bit encoded RF signal; this is wireless encoded data therefore it has to be bit encoded RF signal); at least one sensing parameter is a radiation dose for sensing radiation inside a body (see page 9, lines 30-36); at least one sensing parameter is a temperature for sensing temperature inside the body (see page 9, lines 30-36); the plurality of sensor units are configured to relay data regarding radiation dose and temperature to the reader (see page 9, lines 1-29). Mate in view of Ritter and Knapp provide a therapy system to provide real time dynamic spatial position data and selected internal parameter data of a target region thereto base on data from the at least one sensor and the coupling signal. There has to be a computer program in order for the system to perform this function. Mate and Ritter from claims above provide tracking position data from sensor signal and guiding radiation beam which is the same as dynamic spatial position data from sensors and coupling signal and Knapp provided selected internal parameter data such as radiation and temperature from implanted sensor. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include bit encoded RF signal and sensors as taught by Knapp in order to allow the system to identify and

separately communicate with sensors for sensing temperature and radiation dose inside the patient body.

Response to Arguments

Applicant's arguments filed 10/15/2010 have been fully considered but they are not persuasive. Addressing claims 1 and 42, applicant argues Mates does not disclose an external solenoid on the robotic/articulate arm moveable in three-dimensional pattern to generate a coupling signal that is used to determine the position of the implant or internal solenoid/sensor. Applicant's argument is not persuasive because examiner relies on Ritter to disclose an external solenoid on the robotic/articulate arm moveable in three-dimensional pattern to generate a coupling signal that is used to determine the position of the implant or internal solenoid/sensor (see [0008-0011], [0021-0024] and Fig. 2). Applicant argues Mates teaches away from the use of an external solenoid on the robotic/articulate arm moveable in three-dimensional pattern to generate a coupling signal that is used to determine the position of the implant or internal solenoid/sensor because Mate sensor array is a fix reference structure. Applicant's argument is not persuasive because Mate only discloses the sensors 36 are fixed relative to each other on element 70 and sensor array 34. However, he does not disclose the sensor array 34 is fixed. The sensor array 34 is attach to the movable gantry (see [0035] and [0057]) therefore as the gantry move the sensor array 34 move with it. Mate does not explicitly disclose the sensor array can not be moved therefore Mates does not teach away.

Addressing claims 15-16 and 17-18, applicant argues Mate does not disclose using an external solenoid that generate coupling signal shape, determines angular shift of at least one sensor, much less one that is deconvoluted to determine the location of the implant. Applicant's argument is not persuasive because Ritter discloses this limitation in [0008-0011], [0021-0024] and Fig. 2). The system determines the magnitude and orientation of the internal sensors in the magnetic field produce by an external magnet. This is the same as the claim limitations.

Addressing claims 2, 23, 34, 41, 43-45, 50 and 54-57, applicant argues Mate does not disclose a sensor for sensing internal parameter and radiation. Applicant's argument is not persuasive because Knapp discloses this limitation in page 9, lines 30-36.

Addressing claims 6 and 13, applicant argues the references does not disclose the external solenoid and the internal solenoid, wherein the internal solenoids are configured to cooperate with the external sensor moving in the 3-D pattern outside the body to generate a detectable coupling signal at a depth of up to at least about 14 cm. Applicant argument is not persuasive because Ritter discloses the external solenoid and the internal solenoid, wherein the internal solenoids are configured to cooperate with the external sensor moving in the 3-D pattern outside the body to generate a detectable coupling signal (see [0008-0011], [0022-0024] and Fig. 2). It would have been obvious

design choice to one of ordinary skill in the art at the time of the invention to design the system to detect coupling signal at a depth of up to at least about 14 cm because this enable implant to be deeply implanted anywhere inside the patient body and only require routine skill in the art. The implant/sensor could be implant anywhere in the body at any depth. This only requires ordinary skill and common sense from the surgeon. Other arguments are being address in the rejection section above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached on (571) 272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777